UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America, ex rel. Henry Roop,

Plaintiff,

vs.

Hypoguard USA, Inc. and Medisys Group, PLC,

Defendants.

MEMORANDUM OPINION AND ORDER
Civil No. 07-1600 ADM/AJB

Jeffrey J. Lowe, Esq., Jeffrey J. Lowe, PC, St. Louis, MO, and Bernard E. Reynolds, Esq., Vogel Law Firm, Moorhead, MN, argued on behalf of the Plaintiff.

Brent R. Austin, Esq., Wildman, Harrold, Allen & Dixon LLP, Chicago, IL, and Ryan W. Marth, Esq., Robins Kaplan Miller & Ciresi LLP, Minneapolis, MN, argued on behalf of the Defendants.

I. INTRODUCTION

On September 6, 2007, the undersigned United States District Judge heard oral argument on Defendants Hypoguard USA, Inc. and Medisys Group, PLC's (collectively "Hypoguard") Motion to Dismiss [Docket No. 43]. In this qui tam suit, Plaintiff Henry Roop ("Roop"), suing as a relator on behalf of the United States of America under the False Claims Act, 31 U.S.C. §§ 3729-3733, seeks to recover payments made by Medicare for allegedly defective medical devices and related supplies. For the reasons set forth below, this Court grants Hypoguard's Motion.

II. BACKGROUND[1]

Hypoguard manufactures and sells medical equipment, including the Hypoguard Advance, Assure I, Assure II, Assure III, and QuickTek blood glucose monitoring systems. Compl. ¶ 7 [Docket No. 1]. Roop worked as an account manager and Medicare sales specialist for Hypoguard. Id. ¶ 6. Roop claims that he learned the factual information underlying the Complaint through his employment with Hypoguard. Id. ¶ 6. Roop asserts that Hypoguard's blood testing meters are defective because they require application of a specific amount of blood to operate correctly and do not contain working short-fill detection devices (a device that informs the user when the blood sample is too small to produce an accurate reading). Id. ¶ 30-34. Roop asserts that when a user applies a blood sample that is either too small or too large, the meters produce false readings thus exposing the user to a potential health risk. Id. Roop avers that the false high and low readings demonstrate a defect with Hypoguard's devices that it failed to report to the Food and Drug Administration ("FDA"). Id. ¶ 38. Roop also asserts that Hypoguard knew its meters were defective but continued to sell its meters knowing they would be subject to Medicare reimbursement and thus assisted the submission of fraudulent claims to the government. Id. ¶ 51.

Additionally, Roop asserts that Hypoguard markets the Insuflon, a catheter system, without notifying customers that the device is restricted to sale to adult patients upon order of a physician who can attest to the medical necessity of the device. Id. ¶ 54. Roop asserts that the Insuflon is sold and reimbursed by Medicare without the requisite proof of medical necessity

[1] In considering a motion to dismiss, the pleadings are construed in the light most favorable to the nonmoving party, and the facts alleged in the complaint must be taken as true. Hamm v. Groose, 15 F.3d 110, 112 (8th Cir. 1994).

thus constituting fraud against the government. Id. Further, Roop contends that Hypoguard defrauded the government by selling the device to children without FDA approval. Id.

Roop asserts the United States suffered damage when Medicare reimbursed Hypoguard's customers for the cost of Hypoguard's blood testing meters, when it reimbursed individuals for the cost of the Insuflon catheter without proof of medical necessity, and when it provided reimbursement for a child's use of the Insuflon. Id. ¶ 57. The United States has declined to intervene in this suit.

III. Discussion

A. Motion to Dismiss Standard

Rule 12 of the Federal Rules of Civil Procedure provides that a party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In considering a motion to dismiss, the pleadings are construed in the light most favorable to the nonmoving party, and the facts alleged in the complaint must be taken as true. Hamm, 15 F.3d at 112; Ossman v. Diana Corp., 825 F. Supp. 870, 879-80 (D. Minn. 1993). Any ambiguities concerning the sufficiency of the claims must be resolved in favor of the nonmoving party. Ossman, 825 F. Supp. at 880. "A motion to dismiss should be granted as a practical matter . . . only in the unusual case in which the plaintiff includes allegations that show on the face of the complaint that there is some insuperable bar to relief." Frey v. City of Herculaneum, 44 F.3d 667, 671 (8th Cir. 1995).

Under Rule 8(a) of the Federal Rules of Civil Procedure, pleadings "shall contain a short and plain statement of the claim showing that the pleader is entitled to relief." A pleading must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v.

Twombly, 127 S. Ct. 1955, 1974 (2007).

B. False Claims Act

In order to establish a prima facie case under the False Claims Act ("FCA"), Roop must show that (1) Hypoguard presented a claim, or caused a claim to be presented, to the United States; (2) the claim was false or fraudulent; and (3) Hypoguard knew the claim was false or fraudulent. 31 U.S.C. § 3729(a)(1); see also United States ex rel. Golden v. Ark. Game & Fish Comm'n, 333 F.3d 867, 870 (8th Cir. 2003). A complaint alleging violations of the FCA must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b). United States ex rel. Costner v. United States, 317 F.3d 883, 888 (8th Cir. 2003). Under Rule 9(b), "the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006). In other words, the complaint must allege the "who, what, where, when, and how" of the fraud. Costner, 317 F.3d at 888.

First, Roop asserts that Hypoguard caused the filing of false claims for Medicare reimbursement by selling products it knew to be defective and that it knew would be subject to reimbursement. Compl. ¶ 51. Roop's Complaint fails to meet the particularity requirements of Rule 9(b). Central to Roop's argument that Hypoguard caused a false or fraudulent claim to be submitted to the government is Roop's assertion that Hypoguard's blood glucose monitors are defective. However, Roop does not allege that Hypoguard's monitors failed to comply with any statute or FDA regulation. Indeed, Roop is unable to identify any authority that blood glucose meters requiring a specific blood sample size and that do not contain a short-fill detection device

are defective. Accordingly, this claim fails to allege facts demonstrating any fraudulent act.

Next, Roop asserts that Hypoguard caused the submissions of false claims by selling products the FDA would not have approved but for Hypoguard's fraudulent submission in the pre-market approval process. Id. ¶ 38, 55. Specifically, he asserts that the FDA would not have continued to authorize Hypgoguard's blood glucose meters if Hypoguard had notified the FDA that its monitors sometimes produced false readings. Id. In support of this argument, Roop contends that Hypoguard was required to file medical device reports ("MDR") with the FDA but that Hypoguard failed to file some MDRs and the MDRs it did file contained "false, incomplete and/or misleading information." Id. ¶ 38. This claim also fails to meet the particularity requirements of Rule 9(b). Although Roop contends that Hypoguard provided the FDA with false information during the pre-market approval process, Roop does not allege who within Hypoguard provided the FDA with false information, what the allegedly false information was, or when that information was provided to the FDA (including the date, time, and place). Similarly, Roop's Complaint fails to identify the who, what, where, and when regarding the MDRs Hypoguard submitted to the FDA. Roop does not set forth any specific instances in which Hypoguard was required to submit an MDR but failed to, nor does Roop set forth any specific instances in which Hypoguard either submitted false information in an MDR or neglected to provide required information.

Finally, Roop asserts that Hypoguard caused submission of fraudulent claims to the government because it failed to inform customers that the Insuflon catheter is a device restricted to sale only upon order by a physician and only to adults. Compl. ¶ 54. Again, Roop has not met the requirements of Rule 9(b). Roop does not set forth any facts identifying an instance in

which the Insuflon catheter was actually sold to someone without the requisite physician's determination of medical necessity. Nor does he set forth an example of the Insuflon being sold for a child's use. Roop also fails to set forth any facts demonstrating that a fraudulent sale of the Insuflon has ever occurred, nor the specific conduct Hypoguard engaged in to bring about the fraud.

All of Roop's claims that Hypoguard caused the submission of false claims to the government fail Rule 9(b)'s particularity requirement. Accordingly, this Court must grant Hypoguard's Motion to Dismiss.

C. Leave to Amend

In the memorandum in opposition to Hypoguard's Motion to Dismiss, Roop asks this Court to grant him leave to file an amended complaint if this Court finds that his Complaint fails the requirements of Rule 9(b). Pl.'s Mem. in Opp'n to Defs.' Mot. to Dismiss at 12. Roop has not specified in his memorandum what additional facts he would plead to satisfy Rule 9(b), nor did he submit a proposed amended Complaint. At oral argument, this Court asked Roop's counsel what further facts could be adduced to conform Roop's Complaint to the requirements of Rule 9(b). Roop's counsel responded that he could allege that people were injured by Hypoguard's devices, and continued by stating:

> I guess I could more clearly allege the reimbursement that -- it's not Hypoguard being reimbursed, but that they're causing reimbursements to be made. So I could more specifically allege regarding the MDRs and that they were required to be reported and not reported and provide the basis under the regulations with some evidence as to -- particular evidence as to people that were injured or at least discussion where Hypoguard employees acknowledged that people were injured by the device.

Roop's counsel further requested an additional ninety days to conduct discovery before filing an

amended complaint. The purpose of discovery is not to cure deficiencies in a facially inadequate Complaint.

Rule 15(a) of the Federal Rules of Civil Procedure states that "leave [to amend a complaint] shall be freely given when justice so requires." A court may deny leave to amend when amendment would be futile. Roberson v. Hayti Police Dep't, 241 F.3d 992, 995 (8th Cir. 2001). In this case, the potential amendments Roop's counsel cited would not cure the deficiencies in Roop's Complaint and thus would be futile. The potential amendments do not allege facts demonstrating that Hypoguard's products failed to conform with a statute or FDA requirement, they would not allege any specific instances in which Hypoguard provided the FDA with false information or failed to submit an MDR when it was required to, and they would not demonstrate a specific instance in which a fraudulent claim was filed for the Insuflon catheter because of Hypoguard's conduct. Accordingly, this Court finds that it would be futile to allow Roop to amend his Complaint. Roop's request for leave to amend is denied.[2]

[2] Since the filing of Defendant's Motion to Dismiss, Roop has not sought leave to amend his complaint by submitting to the Court a proposed Amended Complaint as provided by Minnesota Local Rule 15.1.

IV. CONCLUSION

Based upon the foregoing, and all of the files, records and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Dismiss [Docket No. 43] is **GRANTED**; and

2. Plaintiff's Complaint is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: September 24, 2007.